

### **REMARKS**

The Office Action mailed April 18, 2003 has been received and carefully considered. Applicants appreciate the Examiner's comments regarding the Election/Restrictions of claims 35-44, however, Applicants submit that claim 42 and new claims 46 and 47 should not be withdrawn as they are directed to methoxsalen which was originally elected on October 26, 2001. Further, in the Office Action dated November 23, 2001 the Examiner stated:

Applicant's election of the species, methoxsalen is noted. The examiner could not find art on this species, thus the search was extended to the other species. Therefore, the species pilocarpine was examined. (See, November 23, 2001, Office Action, page 3, bottom).

Clearly, a search has been conducted with respect to methoxsalen, and therefore this species has been elected both constructively and expressly (See, Response filed October 26, 2001). Therefore, Applicants believe the claims which should be considered include claims 22, 23, 36, 39, 42, 45-49. New Claims 46-49 are encompassed under the previous species election (methoxsalen) as claims 46 and 47 are directed to methoxsalen itself and claims 48 and 49 are within the purview of the restriction requirement as claim 49 which depends from claim 48 clearly recites methoxsalen as a compound which selectively inhibits CYP2A. Applicants believe the current amended claims and remarks below address the Examiner's remaining concerns.

### **35 U.S.C. §103(a)**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22, 23 and 45 were rejected under 35 U.S.C. § 103(a) as being obvious over Viner (U.S. 5,760,049) for the reasons of record. Viner is purported to teach "a method for controlling tobacco use and alleviating withdrawal symptoms due to the cessation of tobacco use." Additionally, the USPTO stated that Applicants' arguments that the use of "'consisting essentially of' does not necessarily limit the claims as applicants suggests." (See, Office Action page 3). Further, the USPTO has quoted MPEP 2111.03 as requiring that the Applicant has the burden of establishing the "consisting essentially of" language limits the claim. The USPTO

states that “[s]ince applicant’s invention can also have other additives and substances in it as they contend Viner does there is no difference between Viner and applicant in that the compositions both have substances in them besides nicotine and pilocarpine.” While it is true that both Viner and the claimed invention may have other substances in them besides nicotine and pilocarpine, the language “consisting essentially of” in Applicants’ claims require that the additional substances not alter the novel and basic character of the invention. As demonstrated below not only does the claimed invention not include the an acetylcholine receptor antagonist and/or an acetylcholine esterase reactivator but Viner fails render obvious a selection limited to pilocarpine and nicotine as essential components.

Applicants have made it clear that the claimed invention precludes the use of an acetylcholine receptor antagonist and/or an acetylcholine esterase reactivator with the use of the language consisting essentially of in the submitted claims. As cited by the Examiner, MPEP 2111.03 states that for 35 U.S.C. §103 purposes the language “consisting essentially of” will be construed as equivalent to “comprising” “absent a clear indication in the specification or claims of what the basic and novel characteristics actually are.” (See MPEP 2111.03; See also, *In re Janakirama-Rao*, 137 U.S.P.Q. 893, 895-96 (CCPA 1963). In the present case the specification is replete with discussion of both nicotine and CYP2A regulation as the key aspects of enhancing nicotine replacement therapy.

Applicants invention provides nicotine, which itself alleviates withdrawal symptoms. However due to nicotine’s short half, until the present invention, one would have been required to deliver large and frequent doses of nicotine to prevent these withdrawal symptoms and control tobacco use. Applicants invention increases the half life of the nicotine by blocking the physiologic mechanism for its breakdown through the inhibition of CYP2A. In contrast, Viner is silent with regard to the half life of nicotine or ways to prevent nicotine metabolism.

Applicants agree, as the USPTO contends, that Viner teaches “a method for controlling tobacco use and alleviating withdrawal symptoms due to the cessation of tobacco use.” However, Viner’s method requires the use of both an acetylcholine receptor antagonist and an acetylcholine esterase reactivator. The present specification does not discuss the use of oximes to alter an acetylcholine receptors or an acetylcholine esterase just as Viner does not disclose or discuss CYP2A activity or means of altering its activity. Viner is directed to the use of compositions which effect acetylcholine receptors while the claimed invention is directed to

compositions which effect CYP2A activity.

In *Ex parte Davis et al.*, the examiner took the position that a selection of a narrower range of proportions (i.e. eliminating one out of four components) was not patentable. (80 U.S.P.Q. 448, 449 (Dec. 15, 1948). Similar, to the present case the "examiner also state[d] that the expression "consisting essentially of", which occurs in all the claims, is not considered as definitely precluding the presence of ingredients other than those recited." (*Id.* at 449). The applicants in *Davis*, similar to Applicants in the present case asserted that "[a]s to the terminology "consisting essentially of", appellants assert that this would exclude any additionally ingredient, such as the modifier of *Abrams et al.*, which would completely transform or substantially alter the essential character of the adhesive of the claims." (*Id.* at 449). Likewise, Applicants assert that the addition of an acetylcholine receptor antagonist and/or an acetylcholine esterase reactivator would substantially transform the essential character of the claimed invention. In *Davis*, the Court held,

In the present case where the claims recite three ingredients and the reference discloses four, the important question is whether the term "consisting essentially of" excludes that forth ingredient. We think that it does, since the "modifier" materially changes the fundamental character of the three-ingredient composition... We therefore hold that these claims are patentably distinguished in substance from *Abrams et al.*...

In the present case the Applicants invention is even more distinct from the facts of *Davis* in that *Viner* is teaching the importance of two compounds while Applicants are teaching the importance of two completely different compounds with completely different mechanisms of action.

Applicants again direct the Examiner that *Viner* teaches the **primary** components required to alleviate withdrawal symptoms include the use of both an acetylcholine receptor antagonist and an acetylcholine esterase reactivator. Applicants respectfully point out that the method of *Viner* is manifestly different from the method of the claimed invention which recites the use of nicotine and CYP2A modulation. The USPTO cites claim 11, which is ultimately dependent from claim 1, which cites the use of other substances which may include nicotine and pilocarpine as rendering obvious an the claimed invention. The USPTO contends the present invention is obvious because one skilled in the art would have thought to eliminate the critical portion of *Viner*'s teachings (an acetylcholine receptor antagonist and an acetylcholine esterase

*Applicants  
invention  
also  
contains  
other  
ingredients.*

reactivator) and still attempt to alleviate smoking by selectively choosing nicotine and pilocarpine, two components disclosed as optional in Viner's disclosure, to achieve the claimed invention.

Further, one would have to be motivated to eliminate an acetylcholine receptor antagonist and an acetylcholine esterase reactivator without any disclosure by Viner regarding the importance of CYP2A activity and its relationship to nicotine metabolism and smoking. The Examiner in the present case has failed to provide a reason why one skilled in the art would omit both the acetylcholine receptor antagonist and an acetylcholine esterase reactivator from the Viner teaching to achieve the claimed invention. As the Court held in, *In re Stephane Dufauere De Lajarte*, "[t]he examiner has failed to suggest any reason for omitting carbon and sulfur from the Lyle glass....In the absence of any showing why it would be obvious to modify Lyle's glass, a '103 rejection' must be reversed." (337 F.2d 870, 875 (1964)).

Applicants, remind the USPTO that as stated by the Federal Circuit, "a proper analysis under 35 U.S.C. § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicant's disclosure. *Id* at 493. See also M.P.E.P. § 2142.

Applicants point out that the fact that merely showing a claimed product is within a broad field of the prior art and one might arrive at it by selecting specific items and conditions does not render the product obvious in the absence of some directions or reasons in the prior art for making such selections. *Ex parte Kuhn*, 132 U.S.P.Q. 359 (Pat. & Tr. Office Bd. App.)(1961). Indeed, the statutory standard of 35 U.S.C. §103 is whether the invention, considered as a whole, would have been obvious to one of ordinary skill in the art, not whether it would have been obvious for one of ordinary skill in the art to try various combinations. *Akzo N.V. v. E.I. duPont de Nemours*, 1 U.S.P.Q.2d 1705, 1707 (Fed. Cir. 1987). Further, Applicants contend that the fact that pilocarpine and nicotine could have been chosen from the ten possible stimulants of Viner and used together to achieve an embodiment of the disclosure does not render the

Applicant  
hasn't  
explained  
why  
other  
ingredients  
they  
include  
don't  
affect  
their  
invention

invention obvious. Viner provides no discussion of CYP2A activity and therefore no motivation to alter CYP2A activity. Further, Viner lists nicotine as a stimulant and pilocarpine is only mentioned in claim 11 and not in the body of the specification. Essentially, Viner is teaching that both nicotine and pilocarpine may be used for the same purpose, as a stimulant; Viner teaches that nicotine and pilocarpine are interchangeable. Contrarily, Applicants' invention claims the use of nicotine for one physiological effect and the use of a second substance, pilocarpine under the current species being examined, for an entirely different physiological effect, namely the selective inhibition of CYP2A. Where the prior art discloses no particular preference for the component claimed from among a number of other components disclosed in a reference, i.e., where there is no disclosure within the prior art that would have led the routineer to make the critical selections to arrive at the claimed composition, the court found a rejection for obviousness could not be sustained. *Ex parte Wittpenn*, 16 U.S.P.Q.2d 1730, 1731 (PBAI 1990).

Go what!

teaches mixtures of nicotine and pilocarpine.

If motivation for it existed, which it does not, one would still not be motivated to try to use compounds of Viner by eliminating the primary subject matter of the patent to generate method to enhance nicotine replacement therapy. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." (*In re Ratti*, 123 U.S.P.Q. 349 (CCPA 1959); See also, MPEP 2143.01). In the present case the Examiner is suggesting that one would be motivated to modify the operation of Viner by eliminating the two primary components to arrive at the claimed invention when, if anything Viner should be viewed as actually teaching away from the claimed invention.

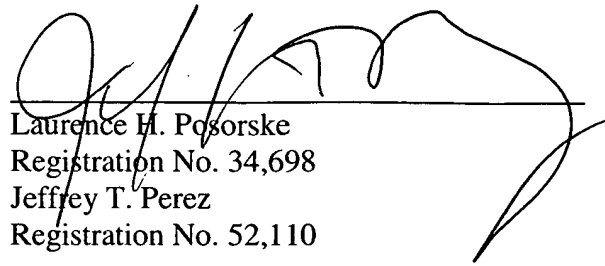
The rejections, to the extent applied against the claims as amended, are respectfully traversed.

**CONCLUSION**

Applicants assert that the above-referenced application is in condition for allowance. Reconsideration and allowance of all pending claims is respectfully requested. Should any outstanding issues remain, the Examiner is invited to telephone the undersigned at 202-955-1500.

Respectfully submitted,

HUNTON & WILLIAMS



Laurence H. Posorske  
Registration No. 34,698  
Jeffrey T. Perez  
Registration No. 52,110

1900 K Street, N.W., Suite 1200  
Washington, D.C. 20006-1109  
Tel: (202) 955-1902  
Fax: (202) 778-2201

Dated: July 18, 2003